

Official Title of the Study: Suturing with U-Technique versus Un-Reapproximated wound Edges during removal of Closed Thoracostomy-tube drain - A single centre Open-label randomized prospective trial (**SUTURE TRIAL**)

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STUDY SUMMARY

Title: Suturing with U-Technique versus Un-Reapproximated wound Edges during removal of Closed Thoracostomy-tube drain - A single centre Open-label randomized prospective trial (**SUTURE TRIAL**)

Background: Closed thoracostomy tube drainage or chest tube insertion is one of the most commonly performed procedures in thoracic surgery. There are several published evidence-based guidelines on safe performance of a chest tube insertion. However, there is absence of prospective controlled trials or systematic reviews indicating the safest technique of closing the wound created at the time of chest tube insertion and that best guarantees good wound and overall outcomes, post-chest tube removal. The use of a horizontal mattress non-absorbable suture or U- suture which is placed at the time of chest tube insertion and used to create a purse-string wound re-approximation at the time of tube removal has been an age-long and time-honored practice in most thoracic surgical settings. It has been established by a recent study that an occlusive adhesive-absorbent dressing can also be safely used to occlude the wound at the time of chest tube removal with good wound and overall outcomes though the study focused on tubes inserted during thoracic surgical operations.

Research Design: The study is an Open-label randomized prospective trial

Methodology: 142 consenting patients with indication for chest tube insertion, who meet the inclusion criteria for enrolment in the study will be randomly assigned into two balanced groups- Group A; that will have a Prolene 1 purse-string suture placed around the thoracostomy wound at the time of chest tube insertion and which will be used for the thoracostomy wound closure at the time of chest tube removal and Group B, that will not have a purse-string suture placement during chest tube insertion and will have their wounds covered by an occlusive adhesive-absorbent dressing material (Primapore*), at the time of chest tube removal. The procedure for chest tube insertion, indwelling chest tube management, post-tube removal care and outpatient follow-up; will be similar for both groups and will follow a pre-determined standardized protocol. Specific clinical outcomes while the chest tube is indwelling and specific clinical and wound outcomes after the chest tube removal will be observed in both Groups for comparison and to determine causal relationships. Observations will be recorded in a specially-designed study proforma.

Principal Exposure: For Group A- Purse-string suture (U-suture technique) placement during chest tube insertion and purse-string suture closure of thoracostomy wound during chest tube removal

For Group B- Non-placement of purse-string suture during chest tube insertion and use of occlusive adhesive-absorbent dressing during chest tube removal, for closure of the thoracostomy wound

Outcome variables:

- Clinical and wound complications with indwelling chest tube
- Early and late wound complications after chest tube removal

Conclusion: Data obtained from the prospective trial will provide general guideline for managing chest tube/thoracostomy wounds after chest tube removal. It will also be employed in the design of institutional protocol for chest tube insertion.

Keywords: Chest tube insertion, Purse-string suture, occlusive adhesive-absorbent dressing, thoracostomy wound closure, wound complications

CHAPTER ONE

INTRODUCTION/BACKGROUND

Closed thoracostomy tube drain insertion also referred to as tube thoracostomy, intercostal drainage or simply chest tube insertion is the most commonly performed surgical procedure in thoracic surgery (1). It is often performed routinely as part of the treatment of many thoracic diseases (2). This procedure largely involves placing a hollow and flexible drainage tube into the pleural space to remove an abnormal collection of air or fluid so as to permit re-expansion of the lung (3,4). It can also be used to infuse agents into the pleural space.

The wide use of chest drains became popular during the 1918 flu pandemic but they were first documented for the treatment of empyema by Hippocrates (5). Around the fourth century B.C, while using rudimentary skills of incision and cautery, he described the process of incising the chest and inserting a metal tube for pleural drainage (5,6).

Generally, the indications for inserting a closed thoracostomy tube drain include-pneumothorax, malignant pleural effusion, empyema and complicated parapneumonic pleural effusion, traumatic haemopneumothorax; postoperatively after thoracotomy, pulmonary lobectomy, oesophagectomy, cardiac surgery; treatment with sclerosing agents or pleurodesis and post-pneumonectomy bronchopleural fistula (4,5,7,8,9). Table 1 below clearly summarizes these indications. The procedure is relatively contraindicated in patients with lung adherence to the chest wall and uncorrected coagulopathy (4).

The chest tubes inserted can be classified based on size or calibre into small-bore chest tubes and large bore chest tubes (9). The small-bore chest tubes (<20Fr) are indicated for spontaneous pneumothorax, free flowing pleural effusions or empyema while the large-bore chest tubes (>20Fr) are indicated for hemothorax, acute trauma, open thoracostomy, after most cardiothoracic, oesophageal or spine surgery (10).

The insertion of a chest tube and the ongoing care of patients with indwelling chest tubes carries the potential for significant morbidity and mortality if not properly done (10). Also, the safe closure of a chest tube insertion wound has been of great interest to surgeons for many years (11). Since chest tube insertion is considered a mandatory skill for different physicians including general and thoracic surgeons, interventional pulmonologists, intensivists and emergency medical specialists worldwide, there is an ever pressing need to develop a standard algorithm for removal of chest tubes (12).

PROBLEM STATEMENT

In spite of the ubiquitous placement of chest drains for different purposes, there is still a lack of high-quality prospectively-designed evidence-based guideline for post-placement management of the chest tubes making current management of patients with chest tubes to be largely reliant on protocols of individual institutions and personal idiosyncrasies mostly borne out of anecdotal experience (13, 14) Several national and international thoracic societies' guidelines exist as well as published literatures that give clear advice on when to consider inserting chest drains (5,7,9). Also, there is a litany of procedural guidelines detailing how to safely perform chest tube insertion. However, there is a paucity of major guidelines or scientifically-proven standard methodology of closing the wound made during the process of chest tube insertion at the time of removal of the chest tube (9,11,15). The conventional method of managing a thoracostomy wound at the time of chest tube insertion is to use an anchoring

suture to fix the chest tube to the wound edge thereby preventing it from spontaneously extruding while also placing a purse-string suture around the wound that would be used to close the wound at the time of chest tube removal (2,11). This purse-string suture can also be used as an additional means of securing the chest tube in position with the added advantage of preventing air or pleural fluid from entering or egressing the pleural space (i.e. air and water tightness) during the tube removal process (2). It has been reported that though beneficial for the most parts, this purse-string suture placement at the time of tube insertion has its inherent burden of suture-related pain, irritation and increased rates of wound infection following its placement and retention, an experience reported by patients during the course of the tube drainage and which may persist even after tube removal (11). It means this conventional method can be associated with higher drain removal pain scores and in addition, more frequent outpatient wound dressings after hospital discharge, need for suture removal after the wound has healed and the long-term development of an unsightly thoracostomy scar (2, 11,16). Skin staplers and simple interrupted skin sutures have also been used with equally unsatisfactory wound outcomes (2).

It has been noted that when petroleum gauze or any other adhesive and impermeant dressing material was used for air and water tight occlusion of the thoracostomy wound after chest tube removal (implying nonuse of a purse-string or any other type of suture), the incidence of iatrogenic pneumothorax and wound dehiscence was higher (2). Other more sophisticated suture techniques such as the use of knotless sutures, using a two-layer method with triclosan-coated sutures; appear to be more expensive to perform and require experience and uncommon expertise (15).

From the foregoing, it is clear that both the conventional suturing method as well as the alternative use of impermeant occlusive dressing of the thoracostomy wound after chest tube removal have their attendant problems. Studies that directly and deliberately compare outcomes and benefits of these two prominent thoracostomy wound management approaches are non-existent in medical literature.

RATIONALE FOR THE STUDY

The lack of evidence to support choice of thoracostomy wound closure at the time of removal of chest tube underscores the need for this study. There is no shortage of publications establishing an association between chest tube insertion as an invasive procedure and the occurrence of specific intervention-related early and late complications with variable degrees of impact on immediate and long-term outcomes of the disease indicating the tube insertion in the first place (4,6,7,9,11-16). Nonetheless, there are a few studies suggesting different techniques of closing a thoracostomy wound at the time of tube removal especially for those inserted following chest trauma as well as post-operation (thoracotomy and sternotomy) in which the tube is often inserted as an adjunct to a specific thoracic surgical procedure (15,16). It limits the generalizability of the findings of such studies knowing other non-traumatic thoracostomy indications abound beyond accidental and intentional trauma of surgery. Also, the review of all other similar studies indicates no universal or consensus decision on the most acceptable thoracostomy wound closure technique with a rarity of discussions about outcome of all suggested techniques especially as it relates to wound failure and cosmesis.

It is instructive to note that, this lack of evidence has contributed to why there is no recognized standardized or consensus method adopted by any of the globally renowned thoracic societies in their clinical practice guidelines as regards the technique of closure of the thoracostomy wound at the time of tube removal and till date controversies still exists about the most superior method amongst the few

described methods. Infact, no single prospective study has been done till date to establish the safest and best closure method that guarantees the best immediate and long-term wound outcomes after chest tube removal. This study is therefore required to answer these pending questions in a prospective manner within a real-life clinical practice setting.

OBJECTIVES OF THE STUDY

GENERAL OBJECTIVES

To prospectively compare the early and long-term outcomes between the use of purse-string (suturing U-technique) and Un-reapproximated thoracostomy wound edges (Occlusive adhesive-absorbent dressing application) at the time of removal of thoracostomy tube drain in patients who have had chest tube insertion.

SPECIFIC OBJECTIVES

- To compare the tube-related complications of chest tube insertion in patients who have purse-string suture (U-suture placement) at the time of chest tube insertion versus those without purse-string suture placement that are enrolled for Occlusive adhesive-absorbent dressing application at the time of chest tube removal.
- To compare the incidence of early complications after chest tube removal in patients who have purse-string suture re-approximation of thoracostomy wound versus those who have only Occlusive adhesive-absorbent dressing application (Un-reapproximated wound edges)
- To compare the incidence of late wound complication after chest tube removal in patients who have purse-string suture re-approximation of thoracostomy wound versus those who have only Occlusive adhesive-absorbent dressing application (Un-reapproximated wound edges)

STUDY HYPOTHESIS

NULL HYPOTHESIS: There is no difference in the wound and clinical outcomes of patients who had purse-string (suturing with U- technique) for closure and those who had an occlusive adhesive-absorbent dressing application (Un-reapproximated wound edges); for post-tube removal management of thoracostomy wound

ALTERNATE HYPOTHESIS: There is a major difference in the wound and clinical outcomes of patients who had purse-string (suturing with U- technique) for wound closure and those who had an occlusive adhesive-absorbent dressing (Un-reapproximated wound edges); for post-tube removal management of thoracostomy wound

STUDY VARIABLES AND DEFINITION

The independent variables to be employed for the analysis include:

- Age of the patient
- Sex of the patient
- Presence of specific co-morbidities (Diabetes, Hypertension, Chronic Liver disease, Chronic kidney disease)
- Charleson Comorbidity Index
- History of cigarette smoking and estimated pack years if positive

- Use of steroids and chemotherapeutic agent
- Abnormal Body mass index (Obesity(BMI> 30kg/m²), Malnutrition(BMI< 18kg/m²))

The Dependent variables to be employed for the analysis include:

- Presence of severe pain at the chest tube site after chest tube insertion (Average daily pain score after tube insertion > 5 on the Visual Analog Scale and or Numerical Rating Scale)
- Occurrence of tube dislodgement after chest tube insertion
- Occurrence of peri-tubal leakage of fluid after chest tube insertion
- Presence of wound air suck-in after chest tube removal (indicated by presence of air suck-in sound through the wound into the pleural space during quiet and or forced inspiration)
- Occurrence of wound infection after chest tube removal (presence of purulent or offensive wound discharge with or without fever or presence of wound discharge that is microbiologically positive)
- Occurrence of wound dehiscence after chest tube removal
- Occurrence of early (within 7 days) and late pneumothorax (more than 1 week) after chest tube removal confirmed on chest radiography
- Development of raised or elevated thoracostomy wound scars (unsightly scars appearing like hypertrophic scars or keloids) within 3 months of chest tube removal

RESEARCH QUESTIONS

- What is the difference in the tube-related complication rates after placing a purse-string suture (U suture placement and retention) for thoracostomy wound re-approximation versus non-placement of purse-string at the time of chest tube insertion?
- What is the difference in the early and late complication rates after using a purse-string suture (U suture) for thoracostomy wound re-approximation versus use of only an occlusive adhesive-absorbent dressing with unreapproximated thoracostomy wound edges; at the time of chest tube removal?
- What is the difference in pain score after using a purse-string suture (U suture) for thoracostomy wound re-approximation versus use of only an occlusive adhesive-absorbent dressing with unreapproximated thoracostomy wound edges; after chest tube removal?
- Is purse-string thoracostomy wound closure associated with more cosmetic complications of thoracostomy scar in the long term than un-reapproximated thoracostomy edges with an occlusive adhesive-absorbent dressing ?

CHAPTER TWO

LITERATURE REVIEW

MANAGEMENT OF THORACOSTOMY WOUND AFTER CHEST TUBE REMOVAL

The common indications for chest tube drainage are listed in Table 1 below. Chest tube insertion is not devoid of risks (17). Closed tube thoracostomy wounds are often classified as “clean contaminated” and hence the risk of wound infection is 7.7% (18). The goal of prophylactic antibiotic therapy for closed tube thoracostomy drainage in traumatic chest injury is to decrease the risk of infectious complications and its associated morbidities, based on reasonable assumptions about the organisms most often cultured (19). Antibiotic prophylaxis should be considered for trauma patients requiring pleural drains, especially after penetrating trauma and a single dose of cephazolin 2g, given intravenously has been suggested, to provide adequate antimicrobial cover (10). A meta-analysis showed that prophylactic antibiotic treatment reduces the risk of developing infectious complications after tube thoracostomy for traumatic injuries of the chest, with the effect best documented for penetrating injuries (16). However, a single-dose antibiotic prophylaxis in penetrating chest trauma is as effective as prolonged prophylaxis (20). Early physiotherapy and early removal of the thoracostomy tube are important to prevent intrathoracic sepsis (20). Antibiotic prophylaxis is not recommended for non-trauma patients requiring a pleural drain (10).

Table 1. The common indications for chest tube insertion (9).	
1) Pneumothorax	Large or symptomatic primary spontaneous pneumothorax Secondary spontaneous pneumothorax Pneumothorax in patients on mechanical ventilation Tension pneumothorax Large or symptomatic iatrogenic/traumatic pneumothorax Occult traumatic pneumothorax associated with hemothorax
2) Pleural effusions	Infected effusion (complicated parapneumonics, empyema) Malignant or benign effusions requiring bedside pleurodesis Hemothorax Chylothorax
3) Postoperation	Thoracic, cardiac, or esophageal surgery Thoracoscopy

The common complications encountered with chest tube insertion are malposition and obstruction, either by occlusion or by kinking; ectopic insertion and tension pneumothorax with significant air leak; hence the need to secure the tube properly (17). Large and medium bore chest drain incisions are usually closed by a suture appropriate for a linear incision(7). Various techniques have been described, but a simple technique of anchoring the tube has not been the subject of a controlled trial (9). A purse string or U-suture placement (horizontal mattress suture) is used to aid removal of the chest drain at a

later date and facilitate closure of the defect on removal of the drain while avoiding the occurrence of an iatrogenic pneumothorax (3,16).

For this technique, the chosen suture should be stout, strong and non-absorbable (silk or prolene) to prevent ease of breakage (7). One or two additional simple or horizontal mattress sutures of generous depth should be placed to properly anchor the tube (7). This suture is also thought to prevent air re-entry on drain removal as well as aid in chest drain site healing by apposing the edges of the wound (16). The suture is often tied to close the skin wound snugly around the tube to prevent any peri-tubal leak (4). However, this can result in an unsightly scar and tying this suture and retaining the knot for the purpose of achieving air and water tightness of the incision can worsen the painful experience of patients before and after drain removal. In addition, any delay in tube removal often increases the risk that is inherently associated with the retained suture being a foreign body (16). In other to increase the cosmetic appearance of the scar as well as provide an airtight seal to prevent air re-entry, attempts have been made to place an absorbable suture at the time of drain insertion but such methods may be cumbersome and complicated (16). Some centers have reported significant success with achieving airtightness using single barbed absorbable suture material(15).

Some commercially available dressings which adhere tightly to the skin and then attach to the drain may also be used but they do not replace the need to stitch the drain firmly in place (10). Another common method is to cover the wound with a water impermeant occlusive dressing material like vaseline gauze or adhesive tape, after removing the chest tubes to prevent air entry into the pleura but the cosmetic result may be unreliable with the wound healing by granulation (11).Petroleum-coated gauze as an occlusive seal was used in the past but it is no longer recommended because it leads to integument breakdown, wound infections, pneumothorax and wound dehiscence (2,7).

Other newer techniques for the management of the chest drain wound after tube removal such as a 2-layer method with triclosan-coated sutures have been described(2). This method was designed with lots of advantages such as non-requirement of a stitch removal at follow-up, good wound healing with cosmetically-appealing scars; without an increased risk of infection but it has a drawback of being too expensive with requirement of technical expertise limiting its widespread adoption (2,3).

Sutures may not be necessary, after all, for closure of chest drain site as a study reported very minimal complications when sutures were not used(16). The study showed that the rate of acute pneumothorax after removal was 1.2% as opposed to the documented rate of 6%-10.7% for purse-string sutures. Late pneumothorax rate was 0% and only superficial infections occurred with this method which did not result in empyema thoracis as opposed to the documented rate of 1%-25% for purse-string suture use (16,21,22). There was also a reduction of the cost per patient which was not just from avoiding using a suture but also avoiding the cost of removing such a suture afterwards (16).

The optimal timing and criteria for tube removal is still a matter of controversy for many reasons (9). Some guidelines state that the criteria for chest drain removal should include no air leak and a 24- hour period of drainage of less than 500 mL fluid(16). Others state that the lung should be fully expanded and there should be no persisting hemothorax or pneumothorax, no air leak, no fresh or altered blood should be leaking from the site of insertion and the daily drainage should be <100 ml(10). Apparently, the timing of removal is dependent on the original reason for insertion and clinical progress and the common grand norm is tube removed when therapeutic goals have been achieved (7,9,16). Some studies recommend that the International Normalized Ratio (INR) should be at least 1.5 and/or platelets greater than $50 \times 10^9 /L$ before the chest tube is removed (10) but this should be regarded as a relative contraindication with decision left to the discretion of the individual managing physician.

When a purse-string suture is intended to be used for wound closure at the time of tube removal, the set up should involve two persons with one tying the knot of the purse-string to appose the wound edges immediately after the other person briskly removes the tube with a firm pull on it, after detaching the tube anchor stitches while the patient performs a Valsalva maneuver or during expiration (7). The actions of the two persons and the patient should be done in a coordinated and synchronous manner to avoid iatrogenic suck-in pneumothorax during the tube removal process. When a simple adhesive Tegaderm p Pad (3M, Saint Paul, MN) dressing was used for occluding the thoracostomy wound at time of tube removal in a study, the chest tube was removed under arrested expiration (the Valsalva maneuver) (16). Studies have demonstrated that the removal of thoracostomy tubes at the end of inspiration or at the end of expiration is equally safe (23). The rule should be that a chest tube should not be pulled out when the patient is still breathing actively because this will result in a pneumothorax (10).

In the study employing occlusive dressing for thoracostomy wound management after tube removal, clinical and wound complication rates (early and late) were significantly lower in comparison to previously published reports on purse-string suture use (16). Though with limitation of being a report from a single surgeon and single institution practice, it was still able to offer a safer alternative to the commonplace practice of purse-string closure technique. Table 2 below summarizes the complications and their rates amongst 312 patients requiring chest tube insertion over an 18-month period in whom only occlusive dressings with Tegaderm p Pad (3M, Saint Paul, MN) was applied to the thoracostomy wound at the time of chest tube removal.

Table 2: Complication and rates after occlusive dressings at time of chest tube removal (16)

Complication	n (%)
Superficial wound infection	5 (1.6)
Acute pneumothoraces	4 (1.3)
Serous discharge requiring suture	1 (0.3)

Though these findings may suggest superiority of this approach to thoracostomy wound management at time of chest tube removal, its reproducibility and generalizability should be done with caution since all the chest tubes were inserted as an adjunct to thoracic surgical procedures.

WOUND OUTCOMES WITH DIFFERENT THORACOSTOMY CLOSURE TECHNIQUES

Properly closing and stabilizing surgical wound edges to restore their original position is a key consideration in achieving good and satisfactory surgical wound outcomes. Surgical wound complications portend poor immediate outcomes for patients as they require more dressings, may require prolonged antibiotic therapy to manage wound infection, experience more pain, and have a strong potential for prolongation of the length of postoperative hospital stay (24,25). Un-interrupted acute wound healing occurring by first or primary intention as a result of the wound edges being in close proximity to each other, tends to heal with far less inflammatory reaction and granulation tissue

formation and minimal wound contraction (26,27). These inevitably result in earlier wound sealing, lower risk of post-operative contamination and infection as well as satisfactory wound pain control.

Also, considering the long term, the main rationale behind closure of surgical wounds is the achievement of far less scarring that will produce a functional and cosmetic-appealing scar when the wound heals (28). There is growing interest in achieving such scars with rising patients' expectations and in turn, increasing surgeons' awareness of surgical materials and techniques required to close surgical wounds to achieve a scar that is functional and with a satisfactory cosmetic appearance (29). Though, several techniques have been proposed and employed to achieve this kind of closure, there is no stand-out ideal technique because each one is fraught with its own inherent and unique challenges.

The early process of any wound healing by primary intention requires the formation and organization of a thin rim of clot holding together the apposing edges of the wound while the wound progressively gains tensile strength (30). The stability and strength of the wound depends largely on the formation and stability of this clot and the biochemical and mechanical forces within the wound bed. These factors counteract the shearing forces at the wound edges that tend to delay wound sealing which should normally be completed in 2 to 3 days (30,31).

Wound suturing is a time-honored technique of enhancing and improving the chances of a wound sealing at the earliest possible time, that has been practiced by surgeons for many generations. The employment of a suture is to achieve primary closure of wounds irrespective of wound length and topography, by maintaining the wound in apposition while it gains strength during the early phases of wound healing. It also helps with early wound sealing.

Despite these undoubted benefits of wound suturing, there exists some inherent side effects like increased risk of wound infection and wound pain in the early post-operative period and the possibility of suture-related undesired scar outcomes. These benefits are often closely related to the make, design and strength of the suture used as well as the technique of placement and application of the suture in wound closure (30,31). The generally acceptable concept is to use a monofilament and non-absorbable suture of good strength to close superficial wounds to limit the side effects of suture use on early and late wound outcomes (29,30,31,32). This has been corroborated by findings from past and recent human and animal studies (33,34,35). Specifically, using prolene suture, a monofilament and nonabsorbable suture, for superficial wound closure towards achieving good early and late wound outcomes had been identified several years ago and the satisfactory early and late wound outcomes have remained incontrovertible till date (36). Prolene is known to cause minimal tissue reaction, to be associated with minimal wound infection and wound pain while also promoting early wound healing with better cosmetic appearance of the scar (36,37).

For over two decades, to mitigate the effect of suture use whilst encouraging a non-invasive apposition of wound edges, in an attempt to promote early wound sealing and satisfactory wound outcomes; occlusive adhesive dressing have taken a progressive pre-eminence in the early management of surgical wounds as described in some series (38). A dressing is described as occlusive if a moist wound surface is maintained while the dressing is in place (38,39). Occlusive dressings are non-invasive, inhibit water vaporization from wound surface to the atmosphere thereby reducing wound desiccation, encourage early wound epithelialization, improve stability of chronic wound granulation tissue and creates a painless autolysis of any wound necrotic area (39,40). Other additional benefits noted include the protection of the wound bed from environmental contaminants and microorganisms with reduction in risk of wound infection , reduction of wound pain, provision of a cost effective wound care option

by decreasing the nursing time required for wound care and ultimately, the production of a less noticeable scar with far more satisfactory cosmetic outcome (40,41,42).

Several commercially available occlusive dressings are available in clinical practice today. A study has utilized Tegaderm p Pad (3M, Saint Paul, MN) for management of thoracostomy wounds which is applied at the time of chest tube insertion (16). Primapore* (Smith & Nephew, London, UK) is an economical all-in-one tape and gauze product (43). The peripheral tape at the margin is adhesive while the central gauze is a soft, comfortable, water-resistant, non-adherent island dressing that ensures patient comfort while also serving as an absorbent medium. This is shown in Figures 1 and 2 below.



FIGURE 1: Primapore* occlusive-adhesive 8.3 x 6cm rectangular dressing

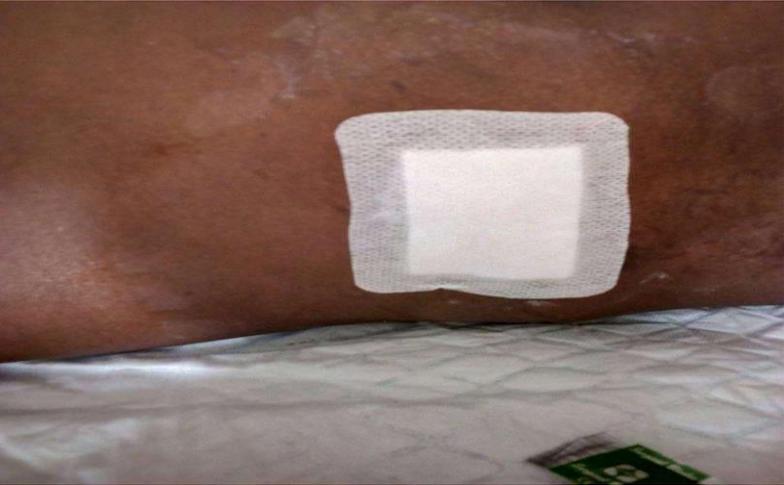


FIGURE 2: Primapore* occlusive-adhesive dressing applied to a thoracostomy wound

CHAPTER THREE

METHODOLOGY

STUDY DESIGN

The study is a prospective randomized open-label clinical trial comparing the outcomes of an unconventional method of closing thoracostomy wounds after chest tube insertion and removal (Occlusive adhesive-absorbent dressing application i.e. Un-reapproximated wound edges) to a common-place conventional method of closure with purse-string suture (U-suturing or purse-string suturing technique). This design entails random allocation of eligible patients into two groups, namely; Group A (patients who will have purse-string suture placed at the time of insertion of chest tube and who will have this purse-string used for the closure of the thoracostomy wound at the time of chest tube removal) and Group B (patients who will have no purse-string placement at the time of chest tube insertion and will have their thoracostomy wound covered with an occlusive adhesive-absorbent dressing at the time of chest tube removal).

STUDY AREA AND SITE

The study will be carried out by the principal investigator and his team at the Division of Cardiovascular and Thoracic Surgery of the Department of Surgery at the University College Hospital, Ibadan (UCH). The hospital is an 850-bed tertiary health institution and a regional reference centre for thoracic surgical and advanced pulmonary medical care that serves mainly the states in South-Western Nigeria including Oyo, Ogun, Osun, Ondo and Ekiti states. It also receives referrals for thoracic surgical cases from Lagos and up-country (South-East, South-South and North-Central regions of Nigeria).

These patients seeking thoracic surgical care are often admitted to designated thoracic surgical and Pulmonary medical wards of the hospital via the emergency department or outpatient clinics.

STUDY DURATION

The study is expected to span a one (1) year period. It will be conducted on all patients who meet the inclusion criteria that present within the study period.

STUDY POPULATION

The study population will be mainly consenting patients who require chest tube insertion for therapeutic purposes and fulfill the inclusion criteria during the study period.

SAMPLE SIZE

The sample size will be calculated by comparing the known incidence rate of 6% for acute pneumothorax when a purse-string suture is used and an incidence rate of 1.2% when the wound edges were un-reapproximated since the occurrence of pneumothorax is the most common morbidity or complication that is documented in the literatures (16). Using the software WinPepi (44), 142 subjects grouped into 71 subjects in group A and 71 subjects in group B will be required to compare a proportion rate of 6% in group A and 1.2% in group B, if level of significance is set at 5%, non-response rate set at 5% with the study powered at 80%; for a two-sided test.

SAMPLING AND RANDOMISATION TECHNIQUES

A block but balanced randomization technique (Unstratified) will be used in determining the use or otherwise of purse-string in the study population. Randomization and intervention assignment into either of the two groups A or B (purse string versus non-purse string) will be determined by grouping labels (A or B) and serialization generated by the soft-ware Winpepi from number 1 to 142 (i.e. Random assignment of 71 in Group A and 71 in Group B).

The generated sequence will be stored on the computer of a blinded research assistant who will be required to inform the team of the next assigned intervention according to the generated sequence, at the time of chest tube insertion for all included and consenting patients. The research assistant will keep record of all assigned labels and ensure all intervention assignment follows the computer-generated sequence in an uninterrupted and reproducible manner.

INCLUSION CRITERIA

Patients who are 18 years of age or older who require chest tube insertion for any of the following indications:

1. Pleural effusion
2. Traumatic or spontaneous pneumothorax
3. Traumatic haemothorax
4. As an adjunct to a thoracotomy for a non-neoplastic and or non –infective condition

EXCLUSION CRITERIA

Any patient so described above who has the following will be excluded:

1. An associated pyopneumothorax
2. Cancer encircling of the chest wall
3. Unconscious with unclear consent situation
4. With infective or neoplastic conditions of the chest wall
5. With individual or family history of wound failure e.g. unsightly scars
6. Who has had irradiation of the chest or chemotherapy administration within 6 weeks from the time of requirement of the chest tube insertion
7. Who is at risk of immunosuppression i.e. diabetes, HIV infection, on steroid therapy, ongoing chemotherapy or who has a congenital or any other acquired immune deficiency state
8. Presence of pleural adhesion during the process of chest tube insertion
9. Those with chest tube malposition after insertion, confirmed on chest radiograph, who will require tube adjustment

INSTRUMENT FOR DATA COLLECTION

Data will be collected using a 7-page structured study proforma as included below (Refer to pages 28-34).

PROCEDURE DETAILS AND DATA COLLECTION TECHNIQUES

1) Before Chest Tube Insertion

In all formally consenting patients who have met the indications for chest tube insertion and participation in this study, the chest tube will be inserted under aseptic techniques. This can be done in the ward at the patient's bedside or in the theatre for post-thoracotomy patients. All chest tube insertion will be performed by the principal investigator or any senior resident doctor in thoracic surgery who has been duly trained to perform this procedure following standard protocols and techniques. The step-by-step guide on how to safely insert a chest tube using the procedural details provided below will be printed out and mastered by all surgeons involved in this study with strict observance of all the required techniques and steps.

As discussed above, a start dose of intravenous third generation cephalosporin antibiotic will be administered prior to the procedure. 1g of Ceftriaxone will be used in this regard in compliance with current practice protocol.

Prior to commencement of the procedure and after formal consent by the patient. The research assistant will be contacted to provide the assigned group for that patient using the computer generated sequence obtained with the WINPEPI software at the beginning of the study.

2) During chest tube insertion

For procedures performed at the patient's bedside, the patient will lie supine or in the cardiac position depending on the diagnosis and clinical condition. The upper limb will be placed under the head for adequate exposure of the safe triangle which is formed by the anterior axillary fold anteriorly, posterior axillary fold posteriorly with the lateral aspect of the sixth rib forming the base. Skin preparation will be done by 10% povidone iodine painting of the anterolateral hemithorax from sternal midline anteriorly to the posterior axillary line and from the clavicle down to the transverse umbilical line. The painting will involve the elbow and finally the axilla will be cleaned. This motion will be carried out thrice to achieve optimal skin sterilization and minimize the risk of contamination.

Thereafter, sterile drapes will be applied to isolate the intercostal space at the mid-axillary line and the surrounding region. The elected site of skin incision is measured using a sterile ruler and marked prior to anaesthesia. Local infiltration of the marked area of skin incision will be done using calculated dose of 2% xylocaine with adrenaline (maximum of 5mg per kg dose). The depth of infiltration should extend to the 5th intercostal space to include the intercostal muscles. After establishing effectiveness of local anaesthesia, a 4cm skin crease incision is then made along the body or lower border of the sixth rib at the mid-axillary line, using a surgical blade and the incision is deepened through the subcutaneous tissue by blunt dissection using a curved number 3 artery forceps or a Kelly forceps. The subcutaneous dissection should create a tunnel extending from the skin incision on the outside to the fifth intercostal space in order to create a superior skin flap. This tunneling is required to create a flap valve-like mechanism aimed at providing an additional method of preventing peritubal leakage after chest tube insertion and development of iatrogenic pneumothorax. The instrument dissection should then be carried through the fifth intercostal space at the upper border of the sixth rib. This is to avoid damage to the subcostal neurovascular structures and also to avoid more pain and haemorrhage.

At this stage, for patients in whom a purse-string suture has been assigned to be used (Group A), a size 0 polypropylene suture is used in making the horizontal mattress or U-shaped purse string as illustrated in Figure 3 below.

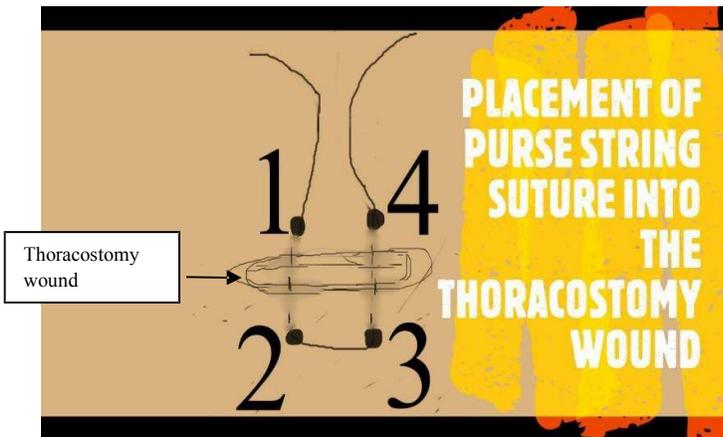


FIGURE 3: Illustration of how the purse-string suture is inserted into the thoracostomy wound

To make this horizontal mattress or U-suture placement or purse-string in the thoracostomy wound, the needle of the suture is inserted from point 1, at 1 cm from the wound edge, through the skin and subcutaneous tissue and then exited through point 2, also 1cm from the wound edge. The needle is then re-inserted through the wound about 2cm along the transverse plane which is point 3. The same motion as performed from point 1 to point 2 is done in a reverse pattern from point 3 to point 4. With this, only the free ends of the suture and the part of the suture between point 2 and point 3 lying on the skin surface will be visible while other parts lie within the thoracostomy wound.

This step of U-suture or purse-string placement will be skipped for all patients assigned to Group B. Thereafter, the blunt dissection is continued with the index finger to the level of the parietal pleura which is breached using the tip of the finger or where the pleural is thickened and fibrotic, with the use of the dissecting forceps. The dissecting finger is introduced into the space to assess for pleural adhesions. As indicated above in the exclusion criteria, all patients with pleural adhesions will be excluded from the study. The intrapleural length of the tube will be estimated from the skin incision to the sternal angle. With the aid of the dissecting forceps, this estimated length of the chest tube with blind-ending external part is then advanced apically and posteriorly into the pleural space.

In both groups, the tube is anchored at the anterior and posterior ends of the wound using size 2 silk sutures placed by narrow horizontal mattress suturing or simple interrupted suturing; to secure the chest tube to the chest wall. For patients in Group A, the placed U-suture or purse-string will be knotted once to create air and water tightness (Figure 4) and the loose ends will also be used to anchor the chest tube by tying the loose ends around the chest for a 2 cm length before making a separate knot on the tube to reinforce the previous silk 2 suture anchorages at both wound ends.

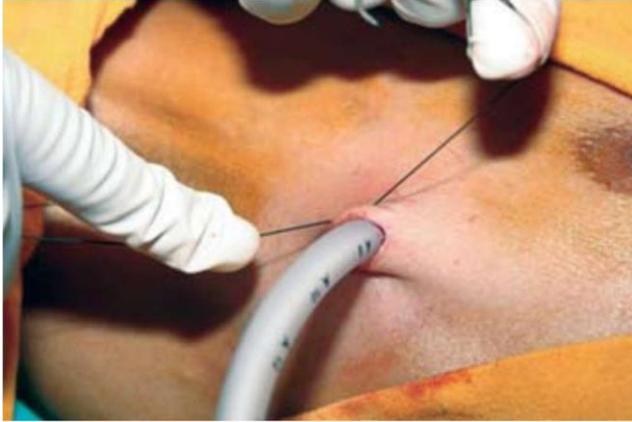


FIGURE 4: Purse string suture tie around the chest tube to achieve air-water tightness. (4)

After this, the tube is clamped and connected to either a flutter-valve bag system or an underwater seal drainage system (9). The site is cleaned and dressing is done using sterile gauze with a light paint of 10% povidone iodine followed by application of a firm plaster.

For large pleural effusions or pneumothorax, the drainage is done gradually in a controlled manner to prevent the development of re-expansion pulmonary oedema.

The details of the technical aspects of the operative procedure of chest tube insertion will be observed as described above in those who have been assigned to either groups that are to have the chest tube inserted as an adjunct to a thoracic surgical procedure (i.e. Operative indication).

3) Management of indwelling chest tubes

A chest radiograph will be done immediately after to ascertain the position of the tube and the degree of lung re-expansion. The drainage of the effluent is measured daily and charted; analgesia (combination of 1g oral paracetamol administered every 6hours at 6am, 12 noon, 6pm and 12 midnight; 50mg oral diclofenac sodium administered every 12hours at 10am and 10pm; and 50mg oral tramadol or 5mg oral morphine administered every 6hours at 9am, 3pm, 9pm and 3am) will be instituted for all patients in compliance with current unit analgesic protocol. All patients requiring therapeutic antibiotics (commenced empirically or with culture sensitivity guidance) will have the antibiotics administered according to the posology of the index medication. This category includes post-operative patients who have had chest tube inserted as an adjunct to surgery and those with any other indication for therapeutic antibiotics. All patients will have incentive spirometry (done with the standard three-ball incentive spirometer, once every hour) and passive physiotherapy (three times a day). Daily dressing of the chest tube site will be done by the unit doctors during the daily ward rounds using 10% povidone iodine as described above. The pain intensity (pain scores) of the patients will be assessed at regular intervals (atleast twice a day; during morning and evening ward rounds) using the visual analogue scale (VAS), numeric rating scale (NRS) and Categorical verbal rating scale (VRS). Even though the VAS and the NRS have been shown to be superior to the VRS in the assessment of acute post-operative pain, all three will be employed in this study to enhance accuracy of assessment and minimize effect of subjectivity on observed pain scores as depicted in Figure 2 below (45).

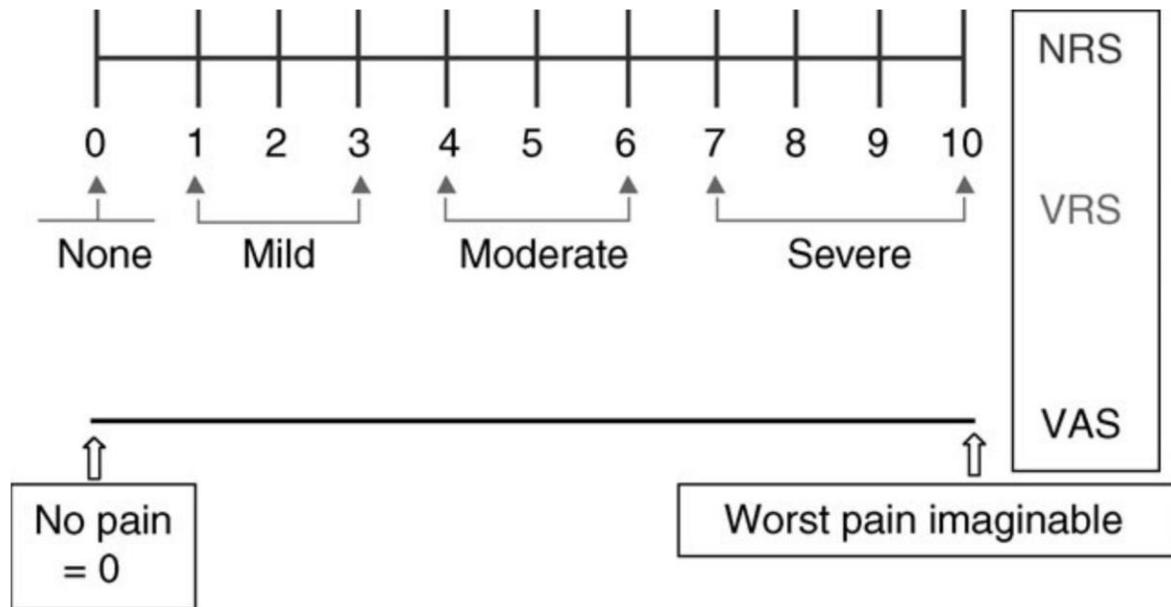


FIGURE 2: The one-dimensional pain intensity scales: the NRS, the VAS and the four-point VRS (45)

The patients with malignant pleural effusion will have pleurodesis done once full lung re-expansion is confirmed by chest radiograph.

The criteria for chest tube removal will include:

- Improved or resolution of the clinical condition
- Change of effluent to serous fluid for all types of pleural fluid collections or cessation of air leak for pneumothorax
- Reduction of volume of daily effluent to less than 100ml in a 24-hour day period
- Evidence of full lung re-expansion on the most current chest radiograph

4) Procedure for chest tube removal

The chest tube will only be removed after satisfactory confirmation by the principal investigator or atleast a senior resident doctor in the unit, that the conditions above have been fulfilled. The chest tube will be removed by two members of the team, one of which must be atleast a senior resident doctor that has been adequately exposed to this protocol.

For patients who had purse-string placement in Group A, the integrity of the suture is first checked to be sure that it is intact, then the anchor stitches are then cut at the limbs to release it from the skin. The chest tube is checked that it is free of attachments to the skin after which the patient is then instructed to make a full inspiratory effort and thereafter arrested expiration. For unconscious patients on ventilator, the intensivist will give a Valsalva manoeuvre of 35 to 40cm H₂O to achieve full inspiration and retains that pressure during the tube removal to simulate arrested expiration.

The lead surgeon (principal investigator or senior resident doctor) makes a surgeon's knot with the purse string without tying it down or snug in preparation for a brisk removal of the chest tube by the

assistance. To ensure synchrony, a short count of one to three is done by the lead surgeon and by the count of three, he completes the knotting down to close the wound just as the tube is rapidly pulled out at a single swipe by the assistance upon completion of the count of three. There will be regular rehearsals and practice of these synchronous actions by all those who will be involved with this study as surgeons and assistants. The wound must be closed to air and water tightness but without strangulating the edges. The suture is trimmed, and a sterile dressing applied as before. There will be strict observance of aseptic technique by all involved in this tube removal process. A chest radiograph is done immediately after to check for presence of iatrogenic pneumothorax. The wound dressing will be removed on the third day and subsequent wound care will be determined by the finding at wound review by the principal investigator on this third day. The protocol to follow will be to continue daily povidone iodine wound care if there is evidence of wound infection but to leave the wound open to fresh air and apply povidone iodine topical cream till the suture is removed by day 7, after tube removal. The pain score will be assessed on a continuous basis (everyday till patient is discharged home and at every contact in the outpatient clinic). The patients will be followed up once a month for atleast 3 consecutive months after chest tube removal. Their pain score, wound outcomes and serial chest radiographic check (immediately after tube removal, at one week after tube removal and at every follow up visit in the outpatient clinic), will be done.

For Group B patients who did not have a purse-string placed during chest tube insertion, the anchor stitches are the cut at the limbs to release it from the skin. The chest tube is checked that it is free of attachments to the skin, the patient is then instructed to make a full inspiratory effort and thereafter arrest expiration. For unconscious patients on ventilator, the intensivist gives a Valsalva manoeuvre of 35 to 40cm H₂O to achieve full inspiration and retains that pressure during the tube removal to simulate arrested expiration. Following the model of synchronized action between two surgeons as described above for Group A patients, the lead surgeon applies the Primapore* occlusive-adhesive dressing firmly at the count of three immediately after the assistant has pull out the chest tube from the pleural space in brisk but in a measured fashion. The occlusive dressing is retained for a atleast three (3) days to allow the wound to seal before it is either changed or removed depending on the wound condition. This decision will be taken by the principal investigator. The protocol to follow will be to change the dressing if the wound is not completely sealed after 3days but to leave it open to fresh air with topical application of povidone iodine cream. If there is evidence of wound infection, the dressing will be done using 10% povidone iodine solution and a sterile gauze. A chest radiograph is done to assess for the presence of pneumothorax (immediately after chest tube removal, at one week after removal and at every outpatient clinic visit). The patients are followed up for once a month for atleast 3 consecutive months after chest tube removal.

5) Follow up and treatment adherence

The patients in both groups will be followed up once every month for atleast three consecutive months assessing for evidence of wound infection, pain control and with chest radiography for evidence of pneumothorax. The wound will also be assessed for development of raised or elevated thoracostomy wound scars (unsightly scars appearing like hypertrophic scars or keloids) within 3 months of chest tube removal.

Patients with wound infection will have 10% povidone iodine daily dressing with institution of antibiotic therapy as per unit protocol. All patients with poor pain control (Pain score greater than 5),

involved with in this study, will have their pain control drug regimen escalated as per unit protocol to achieve better pain control.

DATA ANALYSIS AND MANAGEMENT

The data will be entered into the computer and thorough data cleaning will be done to check for errors and omissions at the end of data collection. The data was analyzed using Statistical Package for Social Sciences (SPSS) version 21. Descriptive statistics for baseline data shall be analyzed using mean, standard deviation, range and median, where appropriate, for any continuous variable and as percentages for any categorical variable. Baseline characteristics of the two study arms will be compared using Chi-square tests (for categorical variables) and student's t-test or analysis of variance (for continuous variables). Risk of complication will be evaluated using Cox-proportional analysis adjusting for potential confounders. Level of significance will be set at 5%. Findings will be presented in forms of texts, tables, figures and graphs as appropriate.

ETHICAL CONSIDERATION

The study will only be commenced after appropriate approval from the Institutional review board is obtained. Informed consent will be obtained from all the participants of this study after the study has been explained in details to them by a member of the team who will be at least a Senior resident that has been trained on the protocol of the study before the commencement of the study. The aims and objectives of the study will be explained to every potential study participant as well as the method of selection. They will be educated about the method of group assignment and the details of the technique inserting chest tube and the different plans of managing the thoracostomy wound indicating the possible complications of wound infection, wound breakdown, iatrogenic pneumothorax, need for frequent dressings, post-procedural pain and increased analgesic requirements as well as need for chest tube re-insertion. The patients will be reassured of the safety of the chest tube insertion procedure. After group assignment by the research assistant, the patient will be informed of the assigned group and requested to complete the informed consent form to authorize the surgeon to proceed with the procedure as per the protocol described above.

The process of obtaining the informed consent will be individualized, the patient or the guardian will be reassured that the information obtained will be protected and not disseminated. Also, the patient will be informed that the decision to participate or decline participation in the study will not affect the quality of treatment that will be offered to them.

The benefit of the study will be explained to them because it will contribute to the knowledge of in management of patients. The findings may also help surgeons in determining when to use purse strings in management of chest tubes. Also, for patients it will help reduce complications related to chest tube insertion and management.

DIVISION OF CARDIOVASCULAR AND THORACIC SURGERY

DEPARTMENT OF SURGERY

COLLEGE OF MEDICINE, UNIVERSITY OF IBADAN,

UNIVERSITY COLLEGE HOSPITAL, IBADAN

INFORMED CONSENT FORM

IRB Research approval number: _____

This approval will lapse on: __/__/__

Title of Research:

Suturing with U-Technique versus Un-Reapproximated wound Edges during removal of Closed Thoracostomy-tube drain - A single centre Open-label prospective randomized trial (**SUTURE TRIAL**)

Name(s) and affiliation(s) of researcher(s):

This study is being conducted by Dr. BAIYEWU L AYODELE, a lecturer and Consultant Cardiovascular and Thoracic Surgeon in the Department of Surgery, College of Medicine, University of Ibadan and University College Hospital, Ibadan.

Sponsor(s) of Research

This research is self-sponsored

Purpose(s) of Research:

The broad aim of this study is to determine which of two methods (approximating the wound edges with a prolene purse-string suture or applying only a Primapore* occlusive-adhesive dressing) of closing a chest tube wound, has a better outcome in the short and long term.

Procedure for the Research, what shall be required of each participant and the approximate total number of participants that would be involved in the research:

Using a block randomization technique, 142 patients will be grouped by a research assistant into two equal groups; 71 patients in Groups A (that will have their chest tube wound closed with a U-shaped prolene suture placed at the time of chest tube insertion) and 71 patients in Group B (that will have their chest tube wound closed with a Primapore* occlusive-adhesive dressing and without wound suturing, at the time of chest tube removal). The pain experience, occurrence of wound infection, chance of air entry into the pleura space after the tube removal and poor cosmetic scar outcome will be studied after the tube removal for up to 3 months. You will be required to take a chest xray immediately after the chest tube insertion, after the tube is removed, one week after and every time you visit us at the outpatient clinic till about 3 months after the tube is removed. Your wound will be checked for infection after the tube insertion and removal and any infection will be treated with wound dressings and appropriate antibiotics. We will control any major pain with appropriate medications till you are fully satisfied and comfortable. If at any time, after the tube has been removed, you require a

chest tube to be re-inserted, it will be at no cost to you. All required information about all participants in this study will be collected and recorded in an anonymized proforma.

Expected duration of research and participant(s) involvement:

You would be involved in the research over a 3-month period. While on admission, after your chest tube insertion, we will obtain some study-related details from you on daily basis and that will continue till you are discharged after the tube has been removed. Once you are discharged, you will be required to visit the outpatient clinic up till 3 months, the frequency of which will be determined by your recovery.

Risk(s):

The only risk that is peculiar to this study is the possibility of requiring another chest tube insertion though from previous knowledge, there is only a little chance. There is no risk to life expected from any intervention to be modified by this study.

Costs to the participants, if any, of joining the research:

You will only be required to pay for the chest tube insertion as expected for any other procedure in the hospital and that will be at the holding rate. All other materials used during the course of the study that in anyway differs from the statutory materials required for the chest tube insertion procedure, shall not be billed to you.

Benefits(s):

You may be able to benefit from a possible non-invasive method of wound closure which will be free of cost. Also, the finding from this study will help in the care of all patients requiring chest tube insertion in the future.

Confidentiality:

All information obtained from participants involved in this study will be coded and personal details will be anonymised.

Voluntariness:

Your participant in this research is entirely voluntary. You are free to withdraw your consent at any time during the study. It will not in anyway influence the way and manner your condition will be managed.

Alternatives to participation:

If you choose not to participate, this will not affect you in any way. You will still have your chest tube inserted in the routine way and at the usual cost.

Due inducements:

No patient will be induced to participate in this study.

Consequences of participants' decision to withdraw from research and procedure for orderly termination of participation:

If you decide to withdraw from the study after you had initially consented, it will have no bearing on the modality of managing your chest tube or following you up at the clinic as all treatments will follow

a standard unit protocol for chest tube management. The principal investigator and his team will attend to you in the standard way without any discrimination.

Modality of providing treatments and action(s) to be taken in case of injury or adverse event(s):

There is no expected injury or adverse effects other than the risk (iatrogenic pneumothorax) described previously and the treatment will be as previously described and it will be entirely free of cost.

What happens to research participants and communities when the research is over:

The research participants and the community will be informed about the research findings through scientific publications. Any of the research participants willing to obtained any non-confidential information about the study will also be obliged.

Statement about sharing of benefits among researchers and whether this includes or excludes research participants:

No direct benefit would be shared among researchers.

Any apparent or potential conflict of interest:

No conflict of interest is declared.

Statement of person obtaining informed consent:

I have fully explained this research to and have given sufficient information, including the risks and benefits, to guide him/her to make an informed decision.

DATE: ____/____/____ **SIGNATURE:** _____

NAME: _____

Statement of person giving informed consent:

The purpose of this study has been explained to me in details. I consent to taking part know that my chest tube wound may be closed using one of two methods which will be determined by a computer-generated grouping. The risks have been explained to me in details. My participant is entirely voluntary. I understand that am free to withdraw my participant at any time. If I withdraw my participation, it will not alter the standard of my care. All information provided by me will be anonymized and kept in confidence.

DATE: ____/____/____ **SIGNATURE/THUMB PRINT:** _____

SERIAL NUMBER: _____

WITNESS' SIGNATURE (if applicable): _____

WITNESS' NAME (if applicable): _____

Detailed contact information including contact address, telephone, fax, e-mail and any other contact information of researcher(s), instructional HREC and head of the institution:

This research has been approved by the UI/UCH Ethical Review Committee and they can be contacted at the IMRAT Building, College of Medicine, University of Ibadan/University College Hospital, Ibadan.

Also, if you have any question about your participation in this research, you can contact the principal investigator,

Name: Dr Baiyewu L Ayodele

Department: Department of Surgery, College of Medicine, University of Ibadan at the University College Hospital, Ibadan.

Phone: +2348034455695

Email: bayan_latyph@yahoo.com

ABRIDGED YORUBA TRANSLATION OF THE CONSENT FORM

Riran egbo pelu okun ti yi o yi egboka yato si pi pa egbo de la yi ran eran po fun egbo to je yo leyin ti a ba yo roba ta fin jo omi ninu aya- Si se iwadii to fo ju an kedere ni ona ase si waju

AWỌN IWỌWỌ TI

E Sa / Ma, A (Ejẹ inu oṣan ati oṣan ninu Ẹkọ Ilera, Ile-iwe giga Ile-ẹkọ giga, Ibadan) wa fun aiye rẹ lati fi orukọ silẹ ninu iwadi ti a darukọ loke. Ẹrọ Iṣoogun ti Arun inu Ejẹ ati Ẹtan Thoracic, Ile-ẹkọ giga Ile-ẹkọ giga University, Ibadan (ti a tọka si nibi CTSU) pẹlu awọn alamọran, awọn onisegun alagbatọ ati awọn ile ile, a wa ninu itoju rẹ pẹlu fifi sii, isakoso ati yiyo awọn apo-inu bi a ti se ipinnu fun o.

Iwadi naa ni ero lati se idanimọ awọn ipa (s) ti lilo awọn gbolohun apamọ ni isakoso awọn alaisan ti o nilo ki o fi sii apo ti o wa fun idalenu ti ipile gbogbo. Iwadi yii yoo se iranlowo ni sise ipinnu ise-sise ni ojo iwaju ti awọn alaisan ti yoo nilo apo-ti-ni-itoju apo lori iwa ti o dara ju ni isakoso ti awọn apo-opa.

Iwadi naa je pataki nitori pe ko si igbekegbe kankan ni orile-edo Naijiria lori idibaje tabi bibeko ti awọn gbolohun apamowo ni fifi sii awọn opon irun. Ifarahan re ninu iwadi yii je pataki bi o se le se iranlowo ninu sise ipinnu ise fun awọn alaisan ti o wa ni iwaju ti o le nilo ki a fi awọn opon irun sii.

Ti o ba gba lati se alabapin ninu iwadi yii, a le fi okun se apere tabi kii se nigbati a ba fi opa ibon sii, gbogbo ilana miiran ti o wa ni fifi sii ti awọn apo-inu yoo see se. Jowo se idaniloju pe boya tabi kii se eriti apamowo ti a lo ninu fifi sii apo apere, a ki yoo se itoju re ni eyikeyi ona bii boya lilo kan ti a fi owo apamowo tabi rara, mejeeji ni awọn ona ti a mo ni fifi sii awọn opon irun. Ipinnu lati lo apamowo kan tabi kii se yoo se nipase egbe CTSU.

A o fi ipalara apere sii nipa lilo ona asejo nipase oṣan ninu awọn onisegun ti o wa ninu egbe CTSU labẹ awọn ilana asejo; Anesitetiki agbegbe yoo wa ni isakoso saaju ki o to ge ti a se lori awo ara re ni apa kanna ti awọn ohun elo apoju. Oṣuwon apamowo le / ni a ko le fi si ibi ti o da lori ipinnu ti kuro, ao fi tube naa si ati ni idaniloju ni ibi nipa lilo awọn irori oran. Okun apo yoo wa ni asopo si ohun elo omi idena ti o ye. A yoo se abojuto tube ati kuro nigbati o toka si.

O yoo nilo lati se awọn idanwo kan ni asiko yii, jowo so fun wa pe awọn wonyi ni o se pataki ninu itoju re ati kii se nitori ikopa re ninu iwadi yii.

Ti o ba gba lati se alabapin ninu iwadi yii, jowo fowosi apa ti o wa ni isale:

Oruko: _____

Ibuwo: _____

Mo ti salaye iwadi yii si oruko ti a daruko loke ti o ti gba lati je apakan ninu iwadi yii.

Oruko: Dr. _____

Ibuwo: _____

Suturing with U-Technique versus Un-Reapproximated wound Edges during removal of Closed Thoracostomy-tube drain - A single centre Open-label prospective randomized trial (SUTURE TRIAL)

STUDY PROFORMA

SERIAL NO:.....

BIODATA:

(1) NAME: _____

(2) PHONE NUMBER: _____

(3) AGE: _____ (4) SEX: _____

(5) OCCUPATION: _____

OTHER INFORMATION:

(6A) LEVEL OF EDUCATION: UNEDUCATED () PRIMARY () SECONDARY ()
TERTIARY ()

(6B)(ROUTE OF ADMISSION: ED () CLINIC () OTHERS

(6C)WARD: ED () ICU () MEDICAL () SURGICAL ()
GYNAECOLOGIC () PAEDIATRICS ()

CLINICAL FEATURES:

(7) COMPLAINT: COUGH () CHEST PAIN () BREATHLESSNESS ()
TRAUMA () FEVER () RECURRENT ()
OTHERS _____

(8) OTHER SYSTEMIC AND ORGAN INVOLVEMENT:

(9) CO-MORBIDITIES: HYPERTENSION () ; DURATION (years) _____

DIABETES () ; DURATION (years) _____

CHRONIC LIVER DISEASE () ; DURATION (years) _____

SKIN LESIONS () ; TYPE _____ ; DURATION (years) _____

CHRONIC KIDNEY DISEASE () ; DURATION (years) _____

CALCULATED CHARLESON COMORBIDITY INDEX _____

OTHERS _____ DURATION; _____

SERIAL NO:

(10) TREATMENT AND DRUG HISTORY:

CHEMOTHERAPY: SPECIFY DRUGS AND DOSE

_____ ; DURATION
_____ ; LAST COURSE _____

IRRADIATION: SITE _____ ; HOW MANY FRACTIONS TAKEN SO FAR
_____ WHEN LAST FRACTION TAKEN (IN WEEKS) _____

STERIODS: Y/N IF YES,
DOSE _____ ; DURATION _____

(11) HISTORY OF WOUND FAILURE: KELOIDS Y/N HYPERTROPHIC SCARS Y/N

(12) PREVIOUS CHEST TUBE INSERTION: YES () NO ()

ADVERSE EFFECT OF PREVIOUS CHEST TUBE: Y/N IF YES, WHICH
REACTION? _____
—

(13) CIGARRETTE SMOKING: YES () NO ()

IF YES, NUMBER OF PACK YEARS: _____

(14) ALCOHOL INTAKE: Y/N , IF YES, DURATION IN YRS _____
ESTIMATED QUANTITY(BOTTLES AND FREQUENCY) _____

EXAMINATION FINDINGS:

(14) PALOR: YES () NO ()

(15) SKIN TURGOR: <2s () >2s ()

(16) DYSPNOEA: YES () NO () NYHA CLASS I, II, III, IV

(17) NEOPLASTIC CHEST WALL DISEASE: YES () NO ()

AFFECTED SIDE: SAME SIDE () CONTRALATERAL SIDE ()

(18) SKIN LESION:

LACERATION: YES () NO () , IF YES, LOCATION _____

SKIN CONTUSION: YES () NO () , IF YES, LOCATION

AVULSION: YES () NO () , IF YES, LOCATION _____

OTHERS: _____

AFFECTED SIDE: SAME SIDE () CONTRALATERAL SIDE ()

SERIAL NO:

(19) THORACOCENTESIS: SEROUS () SEROPURULENT ()
PURULENT () HAEMORRHAGIC () SEROSANGUINOUS ()

(20) WEIGHT _____ HEIGHT _____ BMI _____

INVESTIGATION:

(21) PCV: _____

(22) SERUM PROTEIN: _____; SERUM ALBUMIN _____

(23) CHEST X-RAY FINDINGS

(24) CHEST CT SCAN FINDINGS

(25) PLEURAL FLUID GENE XPRT REACTIVE: YES () NO ()

(26) PLEURAL FLUID CYTOLOGY: MALIGNANT () INFLAMMATORY ()

(27) PLEURAL BIOPSY HISTOLOGY REPORT:

(28) OTHER RELEVANT INVESTIGATION RESULT

CHEST TUBE MANAGEMENT:

(29) SITE OF CHEST TUBE INSERTION: RIGHT () LEFT ()

INTERCOSTAL SPACE _____

(30) SIZE OF CHEST TUBE IN FR: _____

(31) USE OF PROLENE PURSE STRING: YES () NO ()

(32) DURATION OF CHEST TUBE RETENTION:

(33) USE OF THERAPEUTIC ANTIBIOTICS YES () NO ()

IF YES, INDICATE THE GENERIC TYPE , DOSE, FREQUENCY AND DURATION IN DAYS

.....,,,

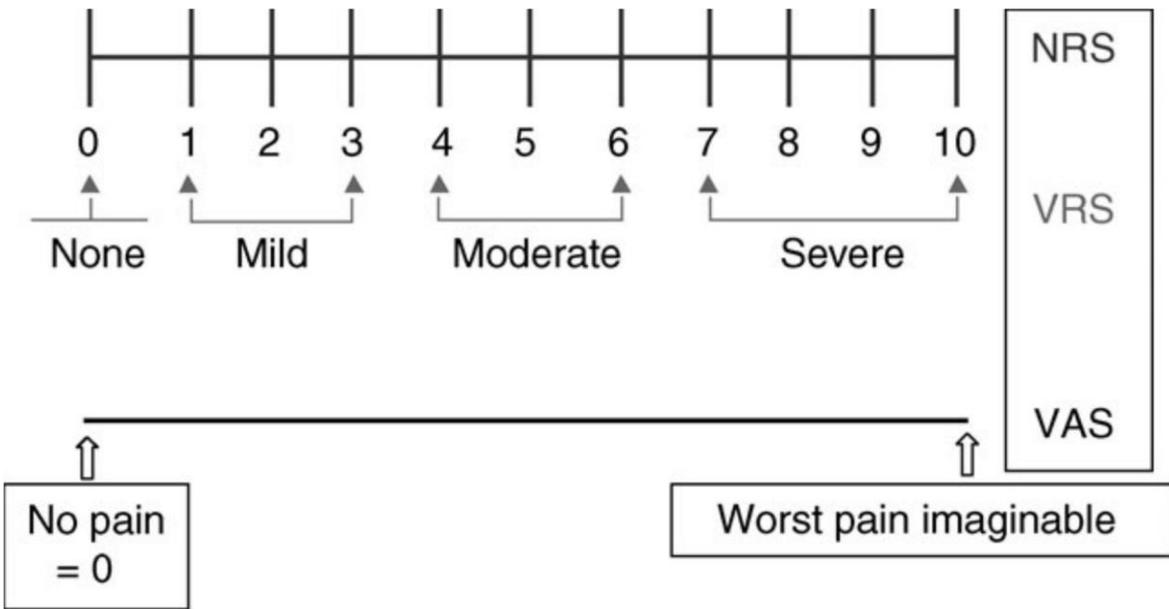
(34) COMPLICATIONS (AFTER CHEST TUBE INSERTION):

PNEUMOTHORAX: YES () NO ()

TUBE DISLOGDEMENT: YES () NO ()

SERIAL NO:

EMPHYSEMA:	YES ()	NO ()
WOUND INFECTION:	YES ()	NO ()
WOUND DEHISCENCE:	YES ()	NO ()
FLUID LEAKAGE:	YES ()	NO ()
AIR LEAK:	YES ()	NO ()
PAIN:	YES ()	NO ()



PAIN SCORE: DAY 1	6AM ()	6PM()
DAY 2	6AM ()	6PM()
DAY 3	6AM ()	6PM()
DAY 4	6AM ()	6PM()
DAY 5	6AM ()	6PM()
DAY 6	6AM ()	6PM()
DAY 7	6AM ()	6PM()
DAY 8	6AM ()	6PM()
DAY 9	6AM ()	6PM()
DAY 10	6AM ()	6PM()

SERIAL NO:

(35) COMPLICATIONS (IMMEDIATELY AFTER CHEST TUBE REMOVAL):

PNEUMOTHORAX ON IMMEDIATE POST-TUBE REMOVAL CHEST XRAY:

YES () NO ()

PNEUMOTHORAX ON CHEST XRAY DONE AFTER 1 WEEK:

YES () NO ()

EMPHYSEMA: YES () NO ()

WOUND INFECTION: YES () NO ()

WOUND DEHISCENCE: YES () NO ()

FLUID LEAKAGE: YES () NO ()

AIR SUCK-IN THROUGH WOUND:

YES () NO ()

MAJOR PAIN: YES () NO ()

PAIN SCORE:

DAY 1 6AM () 6PM()

DAY 2 6AM () 6PM()

DAY 3 6AM () 6PM()

DAY 4 6AM () 6PM()

DAY 5 6AM () 6PM()

DAY 6 6AM () 6PM()

DAY 7 6AM () 6PM()

DAY 8 6AM () 6PM()

DAY 9 6AM () 6PM()

DAY 10 6AM () 6PM()

(36) COMPLICATIONS AT FOLLOW-UP 1

PNEUMOTHORAX ON FOLLOW UP CHEST XRAY:

YES () NO ()

WOUND INFECTION: YES () NO ()

WOUND DEHISCENCE: YES () NO ()

SERIAL NO:

HYPERTROPHIC SCAR: YES () NO ()

KELLOID: YES () NO ()

WOUND PAIN: YES () NO ()

IF YES, PAIN SCORE: _____

COMPLICATIONS AT FOLLOW-UP 2

WOUND INFECTION: YES () NO ()

WOUND DEHISCENCE: YES () NO ()

HYPERTROPHIC SCAR: YES () NO ()

KELLOID: YES () NO ()

WOUND PAIN: YES () NO ()

IF YES, PAIN SCORE: _____

PAIN SCORE: 6AM () 6PM ()

COMPLICATIONS AT FOLLOW-UP 3

WOUND INFECTION: YES () NO ()

WOUND DEHISCENCE: YES () NO ()

HYPERTROPHIC SCAR: YES () NO ()

KELLOID: YES () NO ()

WOUND PAIN: YES () NO ()

IF YES, PAIN SCORE: _____

PAIN SCORE: 6AM () 6PM ()

COMPLICATIONS AT FOLLOW-UP 4

WOUND INFECTION: YES () NO ()

WOUND DEHISCENCE: YES () NO ()

HYPERTROPHIC SCAR: YES () NO ()

KELLOID: YES () NO ()

SERIAL NO:

WOUND PAIN: YES () NO ()

IF YES, PAIN SCORE: _____

PAIN SCORE: 6AM () 6PM ()

COMPLICATIONS AT FOLLOW-UP 5

WOUND INFECTION: YES () NO ()

WOUND DEHISCENCE: YES () NO ()

HYPERTROPHIC SCAR: YES () NO ()

KELLOID: YES () NO ()

WOUND PAIN: YES () NO ()

IF YES, PAIN SCORE: _____

PAIN SCORE: 6AM () 6PM ()

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